

PCT/PTO-1390 (REV. 5-99)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER 1960.236
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) 60/094,809 09/744916
INTERNATIONAL APPLICATION NO. PCT/CA99/00694	INTERNATIONAL FILING DATE 29 July 1999 (20.07.99)	PRIORITY DATE CLAIMED 31 July 1998 (31.07.98)	
TITLE OF INVENTION SMALL VESSEL EXPANDABLE STENT AND METHOD FOR PRODUCTION OF SAME			
APPLICANT(S) FOR DO/EO/US NOVO RPS ULC			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the application time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(I).</p> <p>4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau)</p> <p>b. <input type="checkbox"/> has been transmitted by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</p> <p>b. <input checked="" type="checkbox"/> have been transmitted by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>			
<p>Items 11. to 16. below concern other document(s) or information included:</p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A FIRST preliminary amendment.</p> <p><input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>14. <input type="checkbox"/> A substitute specification.</p> <p>15. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>16. <input checked="" type="checkbox"/> Other items or information: Notif. of Transmittal of the Internat'l Search Report Or Declaration; Internat'l Prelim.Exam.</p>			

17. ☒ The following fees are submitted:**Basic National Fee (37 CFR 1.492(a)(1)-(5):**

Search Report has been prepared by the EP or JPO \$860.00

International preliminary examination fee paid to USPTO

(37 CFR 1.492(a)(1)) \$690.00

No international preliminary examination fee paid to USPTO (37 CFR 1.492

(a)(1)) but international search fee paid to USPTO (37 CFR 1.492(a)(2)) \$710.00

Neither international preliminary examination fee (37 CFR 1.492(a)(1))

nor international search fee (37 CFR 1.492(a)(2)) paid to USPTO \$1,000.00

International preliminary examination fee paid to USPTO (37 CFR 1.492

(a)(4)) and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =

\$1,000.00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months

from the earliest claimed priority date (37 CFR 1.492(e)).

\$

Claims	Number Filed	Number Extra	Rate		
Total Claims	24	-20 = 4	X \$18.00	\$72.00	
Independent Claims	4	-3 = 1	X \$80.00	\$80.00	
Multiple dependent claim(s) (if applicable)			+ \$270.00	\$000.00	

TOTAL OF ABOVE CALCULATIONS =

\$1,152.00

Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement

must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).

\$

SUBTOTAL =

\$1,152.00

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).

\$

TOTAL NATIONAL FEE =

\$1,152.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be

accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +

\$

TOTAL FEES ENCLOSED =

\$1,152.00

Amount to be:

refunded \$

charged \$

a. ☐ A check in the amount of \$_____ to cover the above fees is enclosed.b. ☒ Please charge my Deposit Account No. 50-1710 in the amount of \$ 1,152.00 to cover the above fees. A duplicate copy of this sheet is enclosed.c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1710. A duplicate copy of this sheet is enclosed.**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**SEND ALL CORRESPONDENCE TO: Katten Muchin Zavis
Patent Administrator

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SIGNATURE

RICHARD P. BAUER

January 31, 2001

NAME

DATE

31,588

REGISTRATION NUMBER

1960.236

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
: Examiner: NYA
DONALD R. RICCI, ET AL.)
: Group Art Unit: NYA
Application No.: NYA)
:
Filed: January 31, 2001)
:
For: SMALL VESSEL EXPANDABLE) January 31, 2001
: STENT AND METHOD FOR
: PRODUCTION OF SAME)

Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination on the merits, kindly amend
the above-identified application as follows:

IN THE CLAIMS:

Kindly cancel Claims 1-31 without prejudice

Kindly add Claims 32-55 as follows:

--32. An unexpanded stent comprising a proximal
end and a distal end in communication with one another, a
tubular wall disposed between the proximal end and the distal
end, the tubular wall having a longitudinal axis and a porous
surface defined by a plurality of interconnecting struts, the
stent being expandable upon the application of a radially
outward force thereon to undergo plastic deformation to a

maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

33. The unexpanded stent defined in claim 32, wherein the stent is expandable:

from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation; and

from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

34. The unexpanded stent defined in claim 33, wherein, in the second pre-expanded position, the stent has a diameter greater than about 1.1 mm.

35. The unexpanded stent defined in claim 33, wherein, in the second pre-expanded position, the stent has a diameter sufficiently large for the stent to receive expansion means to further expand the stent.

36. The unexpanded stent defined in claim 33, wherein, in the first unexpanded position, the stent has a diameter less than or equal to about 1.1 mm.

37. The unexpanded stent defined in claim 33, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about to about 1.1 mm.

38. The unexpanded stent defined in claim 33, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about to about 1.0 mm.

39. The unexpanded stent defined in claim 32, wherein the tubular wall has a substantially circular cross-section.

40. The unexpanded stent defined in claim 32, wherein the tubular wall is constructed of a plastically deformable material.

41. A partially expanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent:

having been expanded by the application of a radially outward force thereon from a first unexpanded

position to a second pre-expanded position at which the stent has reached a point of plastic deformation, and

being further expandable upon the application of a radially outward force thereon from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

42. The partially expanded stent defined in claim 41, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter of less than or equal to about 3.3 mm.

43. The partially expanded stent defined in claim 41, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter in the range of from about 2.2 to about 3.3 mm.

44. The partially expanded stent defined in claim 41, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter in the range of from about 2.5 to about 3.0 mm.

45. A stent delivery kit comprising:

a catheter;

an expandable member disposed on the catheter; and

the partially expanded stent defined in claim 41 disposed on the catheter

46. The stent delivery kit defined in claim 45, wherein the stent is mechanically mounted on the expandable member.

47. The stent delivery kit defined in claim 46, wherein the stent is crimped onto the expandable member.

48. A method for mounting an unexpanded stent on a catheter having an expandable member disposed thereon, the unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon:

(i) expanding the unexpanded stent to a second pre-expanded position at which the stent has reached a point of plastic deformation to produce a partially expanded stent; and

(ii) placing the partially expanded stent on the expandable member of the catheter.

49. The method defined in claim 48, wherein Step (i) comprises urging the stent over a mandrel in a direction substantially parallel to the longitudinal axis.

50. The method defined in claim 48, wherein Step (i) comprises pushing the stent over a mandrel in a direction substantially parallel to the longitudinal axis.

51. The method defined in claim 48, wherein Step (i) comprises pulling the stent over a mandrel in a direction substantially parallel to the longitudinal axis.

52. The method defined in claim 50, wherein the mandrel is tapered.

53. The method defined in claim 48, wherein Step (i) comprises urging the stent over a die in a direction substantially parallel to the longitudinal axis.

54. The method defined in claim 48, wherein Step (i) comprises placing the stent over an expandable means, and thereafter expanding the stent to the second pre-expanded position.

55. The method defined in claim 48, wherein Step (ii) comprises crimping the partially expanded stent on to the expandable member of the catheter.--

Applicants' undersigned attorney may be reached in
our Washington, D.C. office by telephone at (202) 625-3500.
All correspondence should continue to be directed to our
address given below.

Respectfully submitted,



Attorney for Applicants

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SMALL VESSEL EXPANDABLE STENT AND METHOD
FOR PRODUCTION OF SAME

TECHNICAL FIELD

5 The present invention relates to an expandable stent and to a method for production of same. More particularly, the present invention relates to an expandable stent particularly suited for deployment in a small diameter body passageway (e.g., a lumen or artery having a diameter of less than or equal to about 3 mm).

BACKGROUND ART

10 Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expandable prosthesis". As used throughout this specification the term "stent" is intended to have a broad meaning and encompasses any expandable prosthetic device for
15 implantation in a body passageway (e.g., a lumen or artery).

In the past ten years, the use of stents has attracted an increasing amount of attention due the potential of these devices to be used, in certain cases, as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the
20 passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct (e.g., natural or iatrogenic) within the human body and can include a member selected from the group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.
25

Stent development has evolved to the point where the vast majority of currently available stents rely on controlled plastic deformation of the entire structure of the stent at the target body passageway so that only sufficient force to maintain the patency of the body passageway is applied during expansion of
30 the stent.

Generally, in many of these systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once

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- the stent has been properly located (for example, for intravascular implantation the target area of the vessel can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is expanded thereby plastically deforming the entire structure of the stent so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to expand the stent (i.e., the applied force exceeds the minimum force above which the stent material will undergo plastic deformation) while maintaining the patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and is subsequently removed.
- 10 Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

See, for example, any of the following patents:

- 15 United States patent 4,733,665 (Palmaz),
United States patent 4,739,762 (Palmaz),
United States patent 4,800,882 (Gianturco),
United States patent 4,907,336 (Gianturco),
United States patent 5,035,706 (Gianturco et al.),
United States patent 5,037,392 (Hillstead),
20 United States patent 5,041,126 (Gianturco),
United States patent 5,102,417 (Palmaz),
United States patent 5,147,385 (Beck et al.),
United States patent 5,282,824 (Gianturco),
United States patent 5,316,023 (Palmaz et al.),
25 Canadian patent 1,239,755 (Wallsten),
Canadian patent 1,245,527 (Gianturco et al.),
Canadian patent application number 2,134,997 (Penn et al.),
Canadian patent application number 2,171,047 (Penn et al.),
Canadian patent application number 2,175,722 (Penn et al.),
30 Canadian patent application number 2,185,740 (Penn et al.),
Canadian patent application number 2,192,520 (Penn et al.),
International patent application PCT/CA97/00151 (Penn et al.),

International patent application PCT/CA97/00152 (Penn et al.), and
International patent application PCT/CA97/00294 (Penn et al.),

the contents of each of which are hereby incorporated by reference, for a
discussion on previous stent designs and deployment systems.

Published International patent application WO 95/26695 [Lau et al. (Lau)]
teaches a self-expandable, foldable stent which may be delivered using a catheter
or other technique. The purported point of novelty in Lau relates to a stent which
may be folded along its longitudinal axis. The folding is accomplished by
conferring bending and twisting stresses to the stent, which stresses, for the
material used to produce the stent, do not exceed that minimum stresses above
which plastic deformation of the stent will occur - i.e., application of these
stresses to the stent results in the storage of mechanical energy in the stent but
does not result in the occurrence of any plastic deformation.

United States patent 5,643,312 [Fischell et al. (Fischell)] teaches a stent
having a multiplicity of closed circular structures connected by a series of
longitudinals. The stent is initially produced in a pre-deployment form
comprising ovals connected by the longitudinals (see Figures 4 and 5). The pre-
deployment form of the stent is then placed on the end of a balloon stent delivery
catheter and the ovals are folded about their minor axis by securing the ovals at
each end of the structure and translating a pair of opposed longitudinals (see
Figure 6).

Many conventional stents rely on plastic deformation of the material from
the stent is constructed for proper deployment. The stress-strain profile is
substantially consistent for a given material (e.g., stainless steel) from which the
stent is constructed. This profile has two specific regions of interest.

The first region is that portion of the profile in which the material exhibits
elastic behaviour. Specifically, the profile is substantially linear (i.e., a
substantially constant slope). During this first region, if the expansive force is
removed, the stent will recoil to near its original diameter - i.e., the material is
still in an elastic state which results in recoil of the stent if the force is removed.

The second region of the profile is reached when the occurrence of recoil is substantially reduced - i.e., the stent will recoil less than 15%, preferably less than 10%, more preferably less than 5%, of the expanded diameter of the stent. Practically, this is the elastic limit of the material. Once this point is reached, the material begins to exhibit plastic behaviour. This second region of the profile has three successive sub-regions of interest along the profile: (i) plastic deformation or yielding; (ii) strain hardening; and (iii) necking.

Once the material begins to exhibit plastic behaviour, continuation of the expansive forces results in a breakdown of the material which causes it to deform permanently - this is known as "plastic deformation" or "yielding". In this sub-region, the stent will continue to expand with substantially no increase in the expansive forces. The term "maximum yield point", when used throughout this specification in the context of an expanding stent, is intended to mean the point on the profile above which an increased expansive force can be applied to the stent to further expand the stent resulting in a decrease in the cross-sectional area of the expanding material. In other words, above the "maximum yield point", the onset of "strain hardening" sub-region of the profile occurs in which the profile rises as a continuous curve to a maximum stress which is also known as the "ultimate stress". Exceeding the ultimate stress leads to onset of "necking" sub-region of the profile in which the cross-sectional area of the stent material decreases in a localized region of the stent. Since the cross-section area is decreasing, the smaller area can only carry a decreasing load resulting in a downward curve from the ultimate stress until the material breaks at the "fracture stress".

Thus, in conventional stents which rely on plastic deformation for deployment, the unexpanded stent is typically in an elastic state (i.e., the first region of the above-mentioned profile) and is expanded to a plastic state (i.e., the second region of the above-mentioned profile), particularly to a point falling with the first sub-region of the latter. Practically, it is generally desirable to deploy the stent to a diameter which is as close as possible to, but does not exceed, the maximum yield point discussed above. The reason for is that the radial rigidity of the stent is maximized.

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One application of stenting which has received little or no attention is that of stenting of small diameter body passageways. As used throughout this specification, the term "small diameter body passageway" is intended to mean an artery or lumen having a diameter of less than or equal to about 3 mm. As used throughout this specification, the term "large diameter body passageway" is intended to mean an artery or lumen having a diameter of greater than about 3 mm.

One likely reason for this is that the conventional stents are designed for implantation into a large diameter body passageway. More specifically, stents which rely on controlled plastic deformation of the entire structure of the stent at the target body passageway are designed to have a maximum yield point at an expansion diameter commensurate with the large diameter body passageway. For most conventional such stents the maximum yield point is reached at a point when the diameter of the expanded stent is about 4 mm to about 5 mm. In the unexpanded state, the diameter of the stent is about 1.5 mm. Such stents are inappropriate for implantation into a small body passageway - i.e., an artery or lumen having a diameter of less than or equal to about 3 mm. This principal reason for this is the dual effect of relatively high recoil forces inherent with such body passageways and poor radial rigidity of the stent if it is expanded to a diameter of less than or equal to about 3 mm - i.e., well below the maximum yield point.

Accordingly, it would be desirable to have an improved stent which overcomes these disadvantages. It would be further desirable if the improved stent could be manufactured readily. It would be further desirable if the improved stent could be deployed using conventional stent delivery systems.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a novel expandable stent which obviates or mitigates at least one of the above-mentioned disadvantages of the prior art.

Thus, in one of its aspects, the present invention provides an unexpanded stent comprising a proximal end and a distal end in communication with one

another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon to undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

In another of its aspects, the present invention provides an unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon:

- from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation; and
- from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

In another of its aspects, the present invention provides a partially expanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent:

- having been expanded by the application of a radially outward force thereon from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation, and
- being further expandable upon the application of a radially outward force thereon from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point. Preferably (but not necessarily), in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter of less than or equal to about 3.5 mm.

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In yet another of its aspects, the present invention provides a stent delivery kit comprising:

a catheter;

an expandable member disposed on the catheter; and

5 a partially expanded stent disposed on the catheter, the stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent:

10 having been expanded by the application of a radially outward force thereon from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation, and

being expandable upon the application of a radially outward force thereon from the second pre-expanded position to a third expanded position wherein the
15 stent will undergo plastic deformation to a maximum yield point. Preferably (but not necessarily), in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter of less than or equal to about 3.5 mm.

In yet another if its aspects, the present invention provides a method for
20 mounting an unexpanded stent on a catheter having an expandable member disposed thereon, the unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being
25 expandable upon the application of a radially outward force thereon:

(i) expanding the unexpanded stent to a second pre-expanded position at which the stent has reached a point of plastic deformation to produce a partially expanded stent; and

(ii) placing the partially expanded stent on the expandable member of
30 the catheter.

Thus, the present inventors have developed a novel stent which is fundamentally different from stents produced heretofore. Specifically, whereas

conventional stents are normally deployed by a single expansion from an initial unexpanded state in which the stent material exhibits elastic behaviour to a fully (i.e., final) expanded state in which the stent exhibits plastic behaviour, the approach in a preferred embodiment of the present invention is based on delivery of a stent which has been pre-expanded to a point of plastic deformation prior to deployment in a subject. Thus, a preferred embodiment of the present stent is deployed using two distinct expansion steps. As will be developed below, in this preferred embodiment, the initial expansion step is conducted *ex vivo* whereas the final expansion step is conducted *in vivo*.

While there are many advantages which accrue from the present stent, the three principal advantages are:

- (i) debulking of the stent - i.e., since the stent is deployed *in vivo* from a pre-expanded state, less material is required to construct the unexpanded stent when compared to an unexpanded stent which is deployed *in vivo* - i.e., the stent may be constructed from a small tube;
- (ii) since the amount of material need to construct the stent is reduced, the flexibility of the stent is improved; and/or
- (iii) the ability to provide a stent having a maximum yield point which is reached at a diameter commensurate (i.e., relative to the prior art) with the typical diameter of a small body passageway.

While the present stent is suited to use with both large body passageways and small body passageways, it is particularly well suited for the latter. From a practical perspective, much of the state of the art in stenting utilizes a low profile balloon mounted on a catheter. Conventionally, this balloon can have a diameter of about 1.0 mm to about 1.3 mm. Since most conventional stents have a final expanded diameter to unexpanded diameter ratio of about 3.0 (this assures that

the point of plastic deformation has been reached and the stent material has been stressed to near the maximum yield point), a conventional stent has a final expansion diameter of 4.5-5.0 mm, making it unsuitable for use in a small diameter body passageway.

5 A novel application of the present stent is to produce the unexpanded stent with a small enough diameter such that the optimal expanded diameter to unexpanded diameter ratio can be reconciled with the desire that the stent material reaches the maximum yield point once the stent is expanded to a diameter of less than or equal to about 3.5 mm, preferably less than or equal to
10 about 3.3 mm, more preferably in the range of from about 2.2 mm to about 3.3 mm, most preferably in the range of from about 2.5 mm to about 3.0 mm. Practically, this has been achieved by designing the stent so that it may be initially expanded to allow it to be mounted on a delivery system - e.g., a conventional low profile balloon mounted on a catheter. Once so mounted, the
15 stent is delivery to the target small diameter body passageway whereupon a second and distinct expansion step is effected to deploy the stent. Thus, as stated above, in a preferred embodiment of the present stent, the initial expansion step is conducted *ex vivo* and the final expansion step is conduct *in vivo*.

To the knowledge of the present inventors, this is the first targeted
20 approach to stenting of small diameter body passageways.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will be described with reference to the accompanying drawings wherein like numerals designate like parts and in
25 which:

Figure 1 illustrates a schematic of an embodiment for producing the present stent in its unexpanded state;

Figure 2 and 3 illustrate a schematic of one preferred embodiment of effecting partial expansion of the unexpanded stent;

30 Figures 4 and 5 illustrate a schematic of another preferred embodiment of effecting partial expansion of the unexpanded stent;

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Figures 6 and 7 illustrate a schematic of mounting of the partially expanded stent produced in Figures 2-5 on to a balloon-mounted catheter;

Figure 8 illustrates the placement in a small diameter body passageway the balloon-mounted catheter have mounted thereon the partially expanded stent;
5 and

Figure 9 illustrates final expansion of the partially expanded stent in the small diameter body passageway.

BEST MODE FOR CARRYING OUT THE INVENTION

10 The specific design of the porous surface is not particularly restricted. Preferably, in the unexpanded state, at least two of the struts meet at the intersection point to define an acute angle.

In the context of the present stent, various repeating patterns in the porous surface of the tubular wall are particularly advantageous. Generally, the preferred
15 repeating pattern is a plurality of intersecting members arranged to define a first repeating pattern comprised of a polygon having a pair of side walls substantially parallel to the longitudinal axis, a concave-shaped first wall having a first apex and a convex-shaped second wall having a second apex, the first wall and the second wall connecting the side walls. Preferably, at least one, more preferably
20 both, of the first apex and the second apex is substantially flat. The first apex and the second apex may be of the same or different length.

Preferably, the side walls comprise longitudinal struts disposed substantially parallel to the longitudinal axis of the stent, each of the longitudinal struts comprising flexure means for substantially complementary extension and
25 compression of a diametrically opposed pair of the longitudinal struts upon flexure of the stent. Practically, the flexure means may comprise at least one lateral section disposed in each longitudinal strut. The lateral section may have a pointed apex, a rounded apex, a flat apex and the like. Further, the flexure means may comprise more than one such lateral per longitudinal strut. If two
30 sections are provided per longitudinal strut, they may be symmetric or asymmetric. Further the two sections may have substantially the same shape and

differing size, or they may have differing shape and size, or they may have substantially the same shape and differing size.

The preferred flexure means comprises an S-shaped portion - e.g., a pair of joined curved sections wherein each curve section has an arc equal to or greater than about 180°. The curved sections may be of substantially the same or different size.

Non-limiting examples of various preferred repeating patterns incorporating some or all of these features and which are useful in the context of the present stent are disclosed in the following copending patent applications:

Canadian patent application number 2,134,997 (Penn et al.),
Canadian patent application number 2,171,047 (Penn et al.),
Canadian patent application number 2,175,722 (Penn et al.),
Canadian patent application number 2,185,740 (Penn et al.),
Canadian patent application number 2,192,520 (Penn et al.),
International patent application PCT/CA97/00151 (Penn et al.) and
International patent application PCT/CA97/00152 (Penn et al.),

the contents of each of which are hereby incorporated by reference. Of course, many conventional repeating patterns may be incorporated into the present stent.

The present stent may be constructed from any suitable starting material. Preferably, the starting material is a thin tube of a metal or alloy. In one preferred embodiment, the starting material may be one which is plastically deformable - non-limiting examples of such a material include stainless steel, titanium, tantalum and the like. In another preferred embodiment, the starting material may be one which expands via temperature-dependent memory (i.e., a material which will expand upon reaching a certain temperature) - non-limiting examples of such a material include balloon expandable nitinol and the like.

With reference to Figure 1, there is illustrated a side elevation of a solid tube 10 of a starting material for producing the present stent. The nature of solid tube 10 is not particularly restricted and includes all materials conventionally used to produce stents. In one preferred embodiment, solid tube 10 is constructed

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of a plastically deformable material. As discussed above, a non-limiting example of such a material is stainless steel. In another preferred embodiment, solid tube 10 is constructed of a material which will expand when a certain temperature is reached. In this embodiment, the material may be a metal alloy (e.g., nitinol) capable of self-expansion at a temperature of at least about 30°C, preferably in the range of from about 30° to about 40°C. Preferably, solid tube 10 has a thickness in the range of from about 0.003 to about 0.015 inches.

If the stent is to be used in a small body passageway, it is preferred that solid tube 10 have a diameter in the range of from about 0.5 mm to about 1.0 mm. If the stent is to be used in a large body passageway, it is preferred that solid tube have a diameter of greater than about 1.0 mm, preferably in the range of from about 1.3 mm to about 1.6 mm.

Solid tube 10 is then subjected to processing which results in removal of a portion thereof to define a porous surface. While the precise nature of this processing is not particularly restricted, it is preferred that the processing be effected on a computer programmable, laser cutting system illustrated generally at 20. Laser cutting system 20 operates by:

- (i) receiving solid tube 10;
- (ii) moving solid tube 10 longitudinally and rotationally under a laser beam to selectively remove sections of solid tube 10 thereby defining a porous surface; and
- (iii) cutting stent sections of desirable length of solid tube 10.

A suitable such laser cutting system is known in the art as the LPLS-100 Series Stent Cutting Machine. The operation of this system to produce the unexpanded stent is within the purview of a person skilled in the art.

Thus, the stent produced from laser cutting system 20 is in the unexpanded state - i.e., the stent will exhibit elastic behaviour in this state.

If desired, the stent may be subjected to further processing to apply a coating material thereon. The coating material may be disposed continuously or discontinuously on the surface of the stent. Further, the coating may be disposed

- on the interior and/or the exterior surface(s) of the stent. The coating material may be one or more of a biologically inert material (e.g., to reduce the thrombogenicity of the stent), a medicinal composition which leaches into the wall of the body passageway after implantation (e.g., to provide anticoagulant action, to deliver a pharmaceutical to the body passageway and the like), a radioactive composition (e.g., to render the stent radioopaque during delivery) and the like.

- The stent is preferably provided with a biocompatible coating, in order to minimize adverse interaction with the walls of the body vessel and/or with the liquid, usually blood, flowing through the vessel. The coating is preferably a polymeric material, which is generally provided by applying to the stent a solution or dispersion of preformed polymer in a solvent and removing the solvent. Non-polymeric coating material may alternatively be used. Suitable coating materials, for instance polymers, may be polytetrafluoroethylene or silicone rubbers, or polyurethanes which are known to be biocompatible. Preferably, however, the polymer has zwitterionic pendant groups, generally ammonium phosphate ester groups, for instance phosphoryl choline groups or analogues thereof. Examples of suitable polymers are described in published International patent applications WO-A-93/16479 and WO-A-93/15775.
- Polymers described in those specifications are hemo-compatible as well as generally biocompatible and, in addition, are lubricious. When a biocompatible coating is used, It is important to ensure that the surfaces of the stent are completely coated in order to minimize unfavourable interactions, for instance with blood, which might lead to thrombosis.
- This good coating can be achieved by suitable selection of coating conditions, such as coating solution viscosity, coating technique and/or solvent removal step. The coating, if present, can be applied to the stent in the pre-expanded or contracted state. Preferably, the stent is applied to the coating in the pre-expanded state to obviate or mitigate the likelihood of damage to the coating during the transition from the contracted (i.e., unexpanded) state to the pre-expanded stated.

With reference to Figures 2 and 3, there is illustrated, in schematic, one preferred embodiment of effecting partial expansion of the unexpanded stent produced in Figure 1. Specifically, there is shown a solid mandrel 50 having a tapered tip 55, and an unexpanded stent 30 produced from laser cutting system 20 (Figure 1). Tapered tip 55 of mandrel 50 is placed one open end of unexpanded stent 30. Thereafter, mandrel 50 is forced into stent 30 in the direction of arrow A. Practically, this can be achieved by keeping mandrel 50 stationary and forcing stent 30 over mandrel 50 or by keep stent 30 stationary and forcing mandrel 50 into stent 30. With reference to Figure 3, as mandrel 50 enters stent 30, tapered tip 55 serves to apply a radially outward force in the direction of arrows B on stent 30 of sufficient magnitude such that the stent reaches the point of plastic deformation - i.e., when mandrel 50 is removed, the partially expanded stent will recoil less than 15%, preferably less than 10%, more preferably less than 5%, of the expanded diameter of the stent. The partially expanded stent is designated 30a.

With reference to Figures 4 and 5, there is illustrated, in schematic, of one preferred embodiment of effecting partial expansion of the unexpanded stent produced in Figure 1. Specifically, there is shown an expandable mandrel 60 having a tapered tip 65 and a series of expandable vanes 70. The diameter of expandable mandrel 60 (in the unexpanded state) is less than that of unexpanded stent 30. Thus, expandable mandrel 60 may be readily placed with stent 30 as illustrated in Figure 4. Once expandable mandrel 60 is placed within stent 30 (preferably the ends of expandable mandrel 60 emanate from the ends of stent 30), the interior of the expandable mandrel is pressurized (e.g., by forcing a fluid into the interior of expandable mandrel 60 or similar means) resulting in application of a radially outward force in the direction of arrows C on stent 30 of sufficient magnitude such that the stent reaches the point of plastic deformation - i.e., when mandrel 60 is removed, the partially expanded stent will recoil less than 15%, preferably less than 10%, more preferably less than 5%, of the expanded diameter of the stent. The partially expanded stent is designated 30a. After partial expansion of stent 30, expandable mandrel 60 is deflated and withdrawn from partially expanded stent 30a. If the stent is to be used in a small body

passageway, it is preferred that the diameter of the partially expanded stent be at least about 1.3 mm, preferably in the range of from about 1.4 mm to about 1.6 mm - i.e., of sufficient diameter to be placed on an expandable member of catheter delivery system.

With reference to Figures 6 and 7, there is illustrated a schematic of mounting of the partially expanded stent produced in Figures 2-5 (or by any other means) on to a balloon-mounted catheter 100. Catheter 100 comprises a balloon 110 mount at a distal end thereof. Balloon 110 is in communication with a tube 115. A guidewire 105 is disposed coaxially within balloon 110 and tube 115. Catheter 100 is conventional and may be, for example, a low profile balloon as discussed above. Balloon 110 is placed within partially expanded stent 30a and crimped (e.g., mechanically) down on balloon 110 in the direction of arrows D (Figure 7). Such mounting of a stents on a balloon is conventional.

Deployment of partially expanded stent 30a will now be described with reference to Figures 8 and 9. Figure 8 illustrates the placement in a small diameter body passageway of the balloon-mounted catheter have mounted thereon the partially expanded stent. Figure 9 illustrates final expansion of the partially expanded stent in the small diameter body passageway.

Thus, there is illustrated a small body passageway 120 have a stenosis 125 therein. Catheter 100 having partially expanded stent 30a mounted thereon is navigated to the stenosis in a conventional manner. On in the proper location, balloon 110 is pressurized (e.g., by forcing a fluid through tube 115 into balloon 100) resulting in the application of a radially outward force on partially expanded stent 30a. Exertion of this force results in further plastic deformation of partially expanded stent 30a until it reaches its fully expanded state 30b at which point stenosis 125 is alleviated - at this fully expanded state, the stent material is close to, but has not exceed, the maximum yield point.

As will be apparent to those of skill in the art, it is important to ensure that, during expansion of partially expanded stent 30a to its fully expanded state 30b, the maximum yield point is not exceeded since this can results in catastrophic failure of the stent. In other words, expansion of the stent should not be at a stress-strain level in the beyond the first sub-region of the second region

of the profile discussed above. With the present specification in hand, those of skill in the art will be readily able to reconcile the following factors to produce a useful stent: (i) specific porous design of the stent, (ii) the material used to construct the stent, (iii) the diameter of tubular material from which the unexpanded stent is made, (iv) stress-strain level at which the point of plastic deformation is reached and (v) stress-strain level at which the maximum yield point is reached.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications of the illustrative embodiments, as well as other embodiments of the invention, will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments.

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What is claimed is:

1. An unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon to undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.
2. The unexpanded stent defined in claim 1, wherein the stent is expandable:
from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation; and
from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.
3. The unexpanded stent defined in claim 2, wherein, in the second pre-expanded position, the stent has a diameter greater than about 1.1 mm.
4. The unexpanded stent defined in any one of claims 2-3, wherein, in the second pre-expanded position, the stent has a diameter sufficiently large for the stent to receive expansion means to further expand the stent.
5. The unexpanded stent defined in any one of claims 2-4, wherein, in the first unexpanded position, the stent has a diameter less than or equal to about 1.1 mm.
6. The unexpanded stent defined in any one of claims 2-4, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about to about 1.1 mm.

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7. The unexpanded stent defined in any one of claims 2-4, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about 1.0 mm.
8. The unexpanded stent defined in any one of claims 1-7, wherein the tubular wall has a substantially circular cross-section.
9. The unexpanded stent defined in any one of claims 1-8, wherein the tubular wall is constructed of a plastically deformable material.
10. An unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon:
- from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation; and
- from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.
11. The unexpanded stent defined in claim 10, wherein, in the second pre-expanded position, the stent has a diameter greater than about 1.1 mm.
12. The unexpanded stent defined in any one of claims 10-11, wherein, in the second pre-expanded position, the stent has a diameter sufficiently large for the stent to receive expansion means to further expand the stent.
13. The unexpanded stent defined in any one of claims 10-12, wherein, in the first unexpanded position, the stent has a diameter less than or equal to about 1.1 mm.

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14. The unexpanded stent defined in any one of claims 10-12, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about to about 1.1 mm.

5 15. The unexpanded stent defined in any one of claims 10-12, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about to about 1.0 mm.

16. The unexpanded stent defined in any one of claims 10-15, wherein the tubular wall has a substantially circular cross-section.

17. The unexpanded stent defined in any one of claims 10-16, wherein the tubular wall is constructed of a plastically deformable material.

18. A partially expanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent:

having been expanded by the application of a radially outward force
20 thereon from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation, and

being further expandable upon the application of a radially outward force thereon from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point.

25

19. The unexpanded stent defined in claim 18, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter of less than or equal to about 3.5 mm.

30 20. A stent delivery kit comprising:
a catheter;
an expandable member disposed on the catheter; and

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a partially expanded stent disposed on the catheter, the stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent:

having been expanded by the application of a radially outward force thereon from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation, and

being expandable upon the application of a radially outward force thereon from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point.

21. The stent delivery kit defined in claim 20, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter of less than or equal to about 3.5 mm.

22. The stent delivery kit defined in any one of claims 20-21, wherein the stent is mechanically mounted on the expandable member.

23. The stent delivery kit defined in claim 22, wherein the stent is crimped onto the expandable member.

24. A method for mounting an unexpanded stent on a catheter having an expandable member disposed thereon, the unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon:

(i) expanding the unexpanded stent to a second pre-expanded position at which the stent has reached a point of plastic deformation to produce a partially expanded stent; and

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(ii) placing the partially expanded stent on the expandable member of the catheter.

25. The method defined in claim 24, wherein Step (i) comprises urging the
5 stent over a mandrel in a direction substantially parallel to the longitudinal axis.

26. The method defined in claim 24, wherein Step (i) comprises pushing the
stent over a mandrel in a direction substantially parallel to the longitudinal axis.

10 27. The method defined in claim 24, wherein Step (i) comprises pulling the
stent over a mandrel in a direction substantially parallel to the longitudinal axis.

28. The method defined in any one of claims 26-27, wherein the mandrel is
tapered.

15 29. The method defined in claim 24, wherein Step (i) comprises urging the
stent over a die in a direction substantially parallel to the longitudinal axis.

30. The method defined in claim 24, wherein Step (i) comprises placing the
20 stent over an expandable means, and thereafter expanding the stent to the second
pre-expanded position.

31. The method defined in any one of claims 24-30, wherein Step (ii)
comprises crimping the partially expanded stent on to the expandable member of
25 the catheter.

FIG. 1.

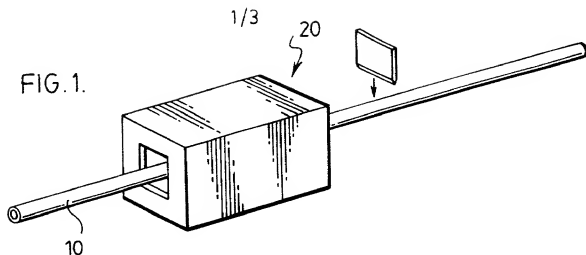


FIG. 2.

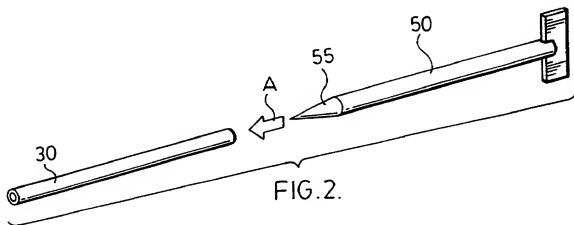
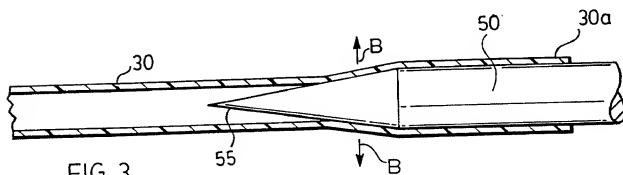


FIG. 3.



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FIG. 4.

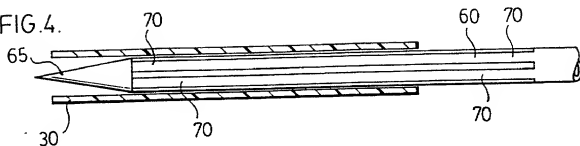


FIG. 5.

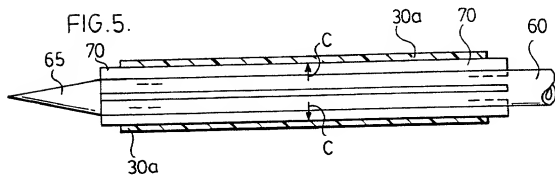
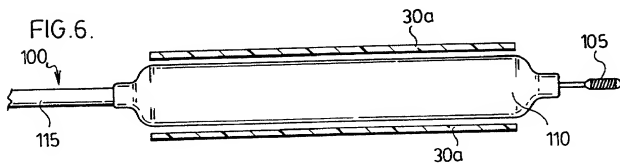
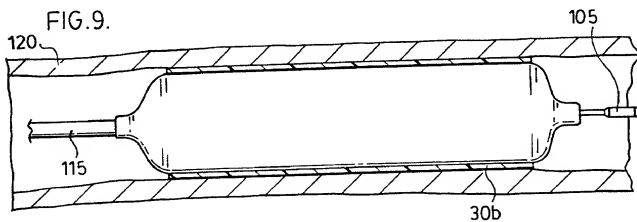
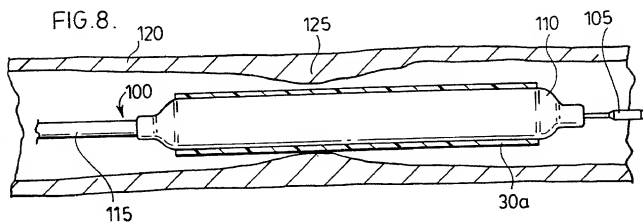
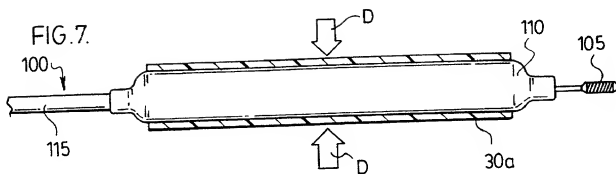


FIG. 6.



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COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

(Page 1)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled SMALL VESSEL EXPANDABLE STENT AND METHOD FOR PRODUCTION OF SAME, the specification of which ☐ is attached hereto ☐ was filed on July 29, 1999 as United States Application No. or PCT International Application No. 09/744,916 and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b), of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designates at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed:

Country	Application No.	Filed (Day/Mo./Yr.)	(Yes/No) Priority Claimed
PCT	CA99/00694	29 July 1999	No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application No.	Filed (Day/Mo./Yr.)
60/094,809	31 July 1996

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to

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(Page 2)

Application No. _____ Filed (Day/Mo./Yr.) _____ (Granted, Pending, Abandoned)

I hereby appoint the practitioners associated with the firm and Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence be addressed to the address associated with that Customer Number:

KATTEN MUCHIN ZAVIS
Customer Number: 27160

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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FOR PATENT APPLICATION

(Page 2)

patentability as defined in 37 C.F.R. §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Application No. Filed (Day/Mo./Yr.) Status
(Patented, Pending, Abandoned)

I hereby appoint the practitioners associated with the firm and Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence be addressed to the address associated with that Customer Number:

KATTEN MUGHIN ZAVIS
Customer Number: 27160

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

(Page 3)

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April 16, 2001

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